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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR         | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|------------------------------|---------------------|------------------|
| 10/586,310            | 05/31/2007  | Maria Margarita Garcia-Calvo | 059893-0121         | 2509             |
| 210                   | 7590        | 01/22/2010                   | EXAMINER            |                  |
| MERCK AND CO., INC    |             |                              | HAQ, SHAFIQU        |                  |
| P O BOX 2000          |             |                              | ART UNIT            |                  |
| RAHWAY, NJ 07065-0907 |             |                              | PAPER NUMBER        |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/586,310 | <b>Applicant(s)</b><br>GARCIA-CALVO, MARIA<br>MARGARITA |  |
|                              | <b>Examiner</b><br>SHAFIQL HAQ       | <b>Art Unit</b><br>1641                                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. The species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The detectably labeled “substituted 2-azetidinone glucuronide” represents a large number of compounds that are structurally and functionally distinct. As for example, the formula (I) and formula (II) compounds that represents “substituted 2-azetidinone glucuronide” are structurally distinct and are expected to be functionally distinct as that contain functionally divergent groups. Further, each of formula (I) and formula (II) represents a large number of distinct compounds when substituted with structurally divergent substitution groups for X, X<sup>1</sup>, X<sup>2</sup>, R, R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> (see pages 32 and 33 of the specification). Therefore, the compounds represented by “substituted 2-azetidinone glucuronide” encompasses a large number of compounds that differ materially in chemical functionality and are structurally diverse and dissimilar compounds, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Also the fields of search are not coextensive. Additionally, besides performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search. Therefore, because of the

reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Therefore, **Applicants are required to elect a single species of a compound represented by “substituted 2-azetidinone-glucuronides” in accordance with the practice set forth in MPEP 803.02 including an exact definition of each and every substitution on the base molecule, wherein a single member at each substitution group or moiety is elected and the elected species must read on the compound from which it depends.**

Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Upon the election of a single disclosed compound, the scope of the invention, inclusive of the elected compound, will be identified by the Examiner for examination along with the elected species. Moreover, whatever specific compound is ultimately

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elected, applicants are required to list all claims readable thereon. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound will be determined. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined.

2. The species described above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative instructions, Annex B, Part 1 (f)(I)(B)(2), the species are not art recognized equivalents.
3. Should applicant traverse on the ground that the compound are not patentably distinct species, applicant should submit evidence or identify such evidence now of

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record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Applicant is advised that a reply to this requirement must also include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(1)

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/  
Primary Examiner, Art Unit 1641